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Chronic pelvic pain in women: An embedded qualitative study to evaluate the perceived benefits of the meridian balance method electro-acupuncture treatment, health consultation and National Health Service standard care.

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INTRODUCTION

Chronic pelvic pain (CPP) is defined as intermittent or constant pain in the lower abdomen or pelvis of at least six months' duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy¹. In an updated systematic review, CPP is estimated to affect 6-27% of women worldwide². Over 1 million women in the UK³ suffer from CPP and this has been highlighted as a key area of unmet need⁴. Some studies suggest that CPP is responsible for 30% of gynaecological consultations and 45% loss of work productivity, leading to significant socioeconomic costs^{5, 6}. CPP can be associated with pathologies such as endometriosis, however about 55% of women with CPP have no apparent underlying pathology⁷. CPP of unknown aetiology is more challenging to treat, with many women not achieving adequate pain relief. Although there is no consensus for the best treatment strategies, non-opioid drugs such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) are often the first line of treatment, progressing to a weak (e.g. codeine, co-codamol), then stronger opioid (e.g. oxycodone) if necessary⁸. Long term use of opioids can be associated with decreased quality of life and physical function⁹, as well as tolerance, dependence and the risk of addiction¹⁰.

Only a few small studies have been undertaken that showed that acupuncture for CPP in women might be effective¹¹⁻¹³. Larger studies comparing acupuncture with sham acupuncture and usual care for other chronic pain conditions, such as osteoarthritis of the knee and tension type headache, have demonstrated some effects^{14, 15}. Most studies, however, mainly focused on the effects of acupuncture needling and ignored the possible effects of traditional Chinese medicine health consultation (TCM HC)¹⁶ and/or the context of an acupuncture treatment¹⁷.

Our hypothesis is that a specific style of acupuncture, the meridian balance method¹⁸ electro-acupuncture (BMEA) combined with TCM HC, may be effective in the management of CPP in women. In our study, the BMEA + TCM HC is called BMEA treatment. Participants who were randomised into the BMEA treatment received TCM HC, had needles inserted into strategic parts of the body and the needles stimulated with micro-current. Needles were stimulated with micro-current because pre-clinical and clinical evidence suggest that EA produces an analgesic effect via the release of endogenous opioid peptides in the central nervous system¹⁹.

The balance method (BM) acupuncture, described in Chong et al²⁰, is one of several styles of acupuncture used in clinical practice. One of the unique features of the BM acupuncture is an algorithm that results in a set of treatment points that are specifically based on the location of pain identified by the patient. Chinese medicine theory postulates a network of 12 meridians (six yin and six yang) on the surface of the body that connect acupuncture points to the internal organs²¹. Pain is believed to be the consequence of the lack of qi (vital energy) and blood, leading to a blocked meridian and an imbalance in the system. To treat the resulting pain, the BM acupuncture balances, for example, a yin meridian with an affected yang meridian and vice versa (the yin/yang concept is a comparison of two opposite but complementary states). The meridian network is best viewed as a conceptual framework to guide clinical practice²⁰. The BM has been described in modern literature^{18, 22, 23} as well as in the seminal classical Chinese medicine text, the Huang Di Nei Jing²⁴.

The health assessment is an integral part of an acupuncture treatment and relates specifically to what our study calls TCM HC. It is a person-centred²⁵ approach that is based on the established clinical practice of Chinese medicine and in itself may have a therapeutic effect^{26, 27}. Participants who were randomised into this group received TCM HC alone. The key aspect of a person-centred consultation is the fostering of a therapeutic relationship with the patient, through active listening and a sympathetic presence, mutual respect and understanding¹⁵. The clinical practice of TCM HC typically includes the four examinations (observation, listening, questioning and palpation) and the eight principles (hot/cold, excess/deficient, yin/yang and interior/exterior)¹⁶. These parameters guide the practitioner/participant interactions, such as how observation, talking, and listening are conducted. Information on the participant's general appearance, body language, emotional status, diet, sleep quality, energy level and the location, as well as the nature of pain, are used to diagnose and promote self-care and wellbeing. A participant is considered yin deficient if she exhibits, for example, a rapid, thin pulse, red tongue with no coating, a subjective feeling of heat, constant thirst and restlessness. Based on these findings, advice is given to follow a diet that predominantly consists of yin nourishing foods such as pumpkins, apples, chicken and pulses and avoids drying foods (deep fried foods and alcohol)²⁸. Subsequent TCM HCs and health advice take into account new concerns and evolving health status.

Included in the present trial was a third comparator, the National Health Service standard care (NHS SC). Participants randomised into this group received the NHS SC which is defined as care and treatment that patients would normally receive from their general practitioner and/or the Edinburgh Centre for Pelvic Pain and Endometriosis Care and Treatment Centre

(EXPPECT Centre), at the Royal Infirmary of Edinburgh. The EXPPECT team comprised a Consultant Gynaecologist, chronic pain Consultant, Psychologist, Specialist Nurse and an Acupuncturist. Treatments could include oral analgesics, anticonvulsants, anti-depressants, hormonal approaches (e.g. combined oral contraceptives or progestogens), or surgical intervention (laparoscopy) if indicated.

Like any intervention, the BMEA treatment, TCM HC alone or NHS SC happened within a context, defined as the overall situation in which any intervention is conducted. These include factors, such as the beliefs and expectations²⁹ of the participant and healthcare provider, the therapeutic setting and nature of the patient-healthcare provider relationships³⁰. These contextual effects are complex and an indivisible part of any intervention but could nonetheless be clinically meaningful²⁶.

AIM

This mixed-methods trial aimed to evaluate the feasibility of a future large-scale randomised controlled trial (RCT) to determine the effectiveness of the meridian BMEA treatment for CPP in women. The primary objectives were to determine recruitment and retention rates. The secondary objectives were to evaluate the effectiveness and acceptability of the methods of recruitment, randomisation, interventions and assessment tools.

We embedded a qualitative arm within a predominantly quantitative study to investigate in more depth the perceived benefits of the BMEA treatment, TCM HC and NHS SC from the participants' perspectives. The present paper presents the qualitative findings of our mixed methods trial. A full description of the quantitative results has now been published³¹. However, a brief summary is offered in the results section.

METHOD

Study Protocol

The study protocol was published online prior to participant recruitment²⁰.

Ethical Approval

Ethical approval was granted by the Scotland Research Ethics Committee (REC 14/SS/1022) in August 2014 and was registered with ClinicalTrials.gov (NCT02295111). Informed written consent was obtained from all participants.

Study Design

Focus group discussions and semi-structured telephone interviews were embedded in a single centre, three-armed feasibility RCT comparing BMEA treatment with TCM HC and NHS SC.

Participant Recruitment and Consent

Between October 2014 and June 2015, 135 patients with CPP who attended the EXPECT Centre, were asked by their Consultant Gynaecologist if they were interested in participating in the study. Clinicians based their decisions to refer on the inclusion/exclusion criteria which were emailed to them prior to the study and made available in all the outpatient areas. Referred patients were approached by a clinical research nurse and provided with a patient information sheet (PIS) to review at home. They had at least 24 hours to review the PIS. If they expressed an interest to participate, they met with a member of the research team for discussion, consent and formal screening. At recruitment and randomisation, further information was given about the embedded qualitative study and participants were invited to take part in their respective focus group discussions. The participants were informed that participation was not mandatory, the discussions would be audiotaped, the anonymised findings presented at local and national meetings and published in peer reviewed journals. Written consents were obtained for the audio-recording of the focus group discussions.

Inclusion Criteria

- CPP longer than 6 months duration
- Average pain score on a numeric rating scale (NRS) of at least 4 out of 10 (0-10) in the previous week
- Women aged 18 years or over
- Able and willing to comply with the interventions

Exclusion Criteria

- Pregnancy
- Malignancy
- Severe bleeding disorders (e.g. type 2, 3 Von Willebrand disease)
- Taking regular anti-coagulant
- Severe needle phobia
- A pacemaker in situ
- A history of seizures
- Treatment with EA and meridian BM within the last 6 months
- Moderate to severe psychiatric illness and under the care of a psychiatrist

Sample Size

A sample size of 30 participants allowed an estimation of the rates of recruitment and retention to within a standard error (SE) of at most 10%. For the focus group discussions, we had aimed to have 15 participants (5 per group).

Interventions

After written consent was obtained, 30 eligible women were randomised to receive either the BMEA treatment (group 1, TCM HC (group 2) or NHS SC (group 3). Group 1 received 8 BMEA treatment interventions twice a week for 4 weeks. Group 2 received 8 TCM HC interventions twice a week for 4 weeks, group 3 received NHS SC.

Assessment Tools

Three focus group discussions, each lasting for about 60 minutes were conducted by an independent qualitative researcher post study end point questionnaire completion. A set of validated pain, physical and emotional questionnaires (e.g. Numeric Rating Scale [NRS]³², Brief Pain Inventory [BPI]³³ and Hospital Anxiety and Depression Scale [HADS]³⁴) was given to all participants at baseline (0), 4, 8, and 12 weeks. Additionally, we conducted semi-structured telephone interviews to assess the acceptability of the methodology of the study to participants, as this information was not captured in the focus group discussions.

Topic Guide

The topic guides for the BMEA treatment, TCM HC and NHS SC groups were developed to explore the participants' experience of the trial (Figure 1).

Thematic Analysis

The datasets from the focus group discussions were transcribed verbatim and thematically analysed³⁵. This began with active immersion through repeated listening to the recordings as well as repeated reading of the dataset to identify patterns and meanings while making notes or ideas. This iterative approach enabled a thorough analysis of the complex focus groups dataset, highlighting what was unique and common to the participants' perception of the benefits of their respective interventions, resulting in a list of data extracts for the generation of meaningful codes. These codes were grouped according to their commonalities, resulting in five main themes shared by the BMEA treatment and TCM HC groups, and four main themes in the NHS SC group. The analysis was performed manually by the first author and reviewed by the last author who read the coded data to ensure there was agreement on the initial coding. She also reviewed a sample of original interviews to make sure all relevant data had been coded. This also ensured that the datasets were not taken out of context as well as validating the interpretation. A degree of inductive process was adopted during the analyses which was also

guided by the step-by-step thematic analysis.

Epistemology and Interpretation of Datasets

This study was conducted from a pragmatist perspective which favoured more than one method of data collection to answer the problems under scrutiny. Pragmatism emphasized the practicality of undertaking research and the recognition of both subjective (participant's lived experience) and objective knowledge³⁶. Except for the focus group discussions, the research was undertaken by the first author as part of her PhD thesis. The first author is an experienced health care professional in nursing and has over 17 years of clinical experience in acupuncture. She has a Master of Science Degree in Acupuncture from an accredited school in New York City, USA. She was awarded a PhD by The University of Edinburgh for her research in Acupuncture for Chronic Pain Management. She has no personal experience of CPP.

RESULTS

Quantitative Results Summary

Of the 135 women who attended EXPECT Centre during the recruitment phase, 59 (44%) were referred. Of these 59 women, 30 (51% of those referred) were randomised into the study. Of the 30 participants, 11 participated in the three focus group discussions, six participants from the BMEA treatment, two from TCM HC and three from NHS SC groups; eight from the BMEA treatment, five from the TCM HC and eight from the NHS SC responded to the semi-structure telephone interviews. (Figure 2, CONSORT Diagram). Table 1 shows the participants' characteristics.

The retention rates were 80% (95% CI 74-96), 53 % (95% CI 36-70) and 87% (95% CI 63-90) in the BMEA treatment, TCM HC and NHS SC groups respectively. This showed a borderline significant difference between the groups (χ^2 test, $p=0.08$), however, the number of participants in the trial was small. Attendance rates for the BMEA treatment group was 90% compared to 56% in the TCM HC group (χ^2 test, $p<0.001$).

Outcome measures between groups and per group were analysed to give an indication of which measures might be likely to show an intervention effect in a larger RCT. A higher proportion of those who received the BMEA treatment had a clinically significant reduction in NRS-pain score and sleep interference (BPI) at weeks 4 and 8 when compared to the groups who received TCM HC and NHS SC. Fishers' Exact test did not show a statistically significant difference. Estimates of effectiveness per group suggested a trend towards improvement in the BMEA treatment group at week 4 for example in pain and sleep interference scores. The TCM HC group showed improvements in some scores such as Brief Pain Inventory (BPI) severity and

interference. There was little change in the NHS SC group, except in the Hospital Anxiety and Depression Score (HADS) -total mean change by week 8 and 12, where the participants showed a statistically significant increase (mean difference=4.0, 95% CI 0.2 to 7.8, $p=0.04$; and mean difference=3.4, 95% CI 0.2 to 6.7, $p=0.04$, respectively), i.e. more depressed and anxious, while group 1 achieved a significant (mean difference=-2.5, 95% CI -7.4 to -0.4, $p=0.04$) change from baseline to week 4 in the opposite direction i.e. less anxious and depressed.

Focus Group Discussions Key Findings

The five common themes that pertained to the perceived benefits by the participants of the BMEA treatment and TCM HC groups were: pain reduction, enhanced sleep, wellbeing, energy and coping skills. The four themes that emerged from the analysis of the focus group discussion datasets of NHS SC group were: adverse effects of medications, frustrations at the lack of effectiveness of medications, heavy reliance on drugs and services that are helpful. Of note was that both the BMEA treatment and NHS SC groups shared the narratives of the negative impact of living with CPP, even though we did not set out to investigate this aspect. Thus, we will not report in detail here but suffice to say that these participants experienced negative impact on their employment, intimate lives, ability to carry out household chores, self-worth and social isolation. The results of the semi-structured telephone interviews are reported below, followed by the key findings of the focus group discussions and a summary of the quantitative results.

Perceived benefits of TCM HC and BMEA treatment

Theme 1: Pain Reduction

The participants in the TCM HC group reported a reduction in pain but were careful to state that other events such as surgery could have contributed to their pain reduction:

... Sometimes I think, yes...and then every now and again I think, no, but...on balance I think, yeah...yes...Yeah...it has helped... (Participant 2, TCM HC group)

...erm, as for my pain levels, well, I think they got better after that...for sure...I did have surgery in June which...really, really helped...for a while...so...And that obviously, you know, complicates whether I can say it's...just from the health consultation or not. (Participant 1, TCM HC group)

Most participants in the BMEA treatment group reported short-term pain relief which they said was a welcome break from the constant debilitating pain:

....I found it a godsend. It took my pain away for a day, two days after the treatment...which I hadn't had in over six years, so...it made a big difference, I felt I had energy...(Participant 6, BMEA treatment group)

Theme 2: Enhanced Sleep

A mixed pattern of sleep was reported by participants in the TCM HC group:

Well, I take amitriptyline.... I slept well on that... Prior to that...my sleep wasn't great...so I probably can't say that...my sleep's, er...any better because of anything...to do with the...study. (Participant 2, TCM HC group)

Er ..I'm pretty sure that mine is definitely improved because of that... It's really improved so...(Participant 1, TCM HC group)

Similar to the pain free experience, a majority of the participants in the BMEA treatment group reported that they enjoyed better sleep:

I went through about four years, eh, either pacing the floor at night time or having broken sleep....It just wears you out, it makes your pain worse, it just makes everything worse...When I started on my acupuncture, I could sleep through the night...That was the best bit....Happy mummy. (Participant 3, BMEA treatment group)

Theme 3: Enhanced Energy

Some participants experienced more energy:

...it was helping me so I had more energy...so I just thought I was just like Wonder Woman...first couple of times I was coming home and everything was getting done in the same day. Um, and then after that I was like that, no, just...just stop. [laughs] (Participant 3, BMEA treatment group)

...I felt like I had more energy, I felt more bubbly type thing...although the pain was still there... (Participant 1, BMEA treatment group)

A participant in the TCM HC group thought that her enhanced energy level was from learning to pace herself:

But I th...think on the...longer term...I think it has. And that might be something to do with me pacing myself a bit...better. (Participant 2, TCM HC group)

Theme 4: Enhanced Wellbeing

The TCM HC and BMEA treatment groups reported an enhanced sense of wellbeing. They spoke of being emotionally stronger and happier following their respective interventions. Participants in the TCM HC group reported that the consultation had helped them cope better and consequently feel happier. The key for the TCM HC group was timing. A participant

described the impact of TCM HC as long lasting and offering what she needed most at that stage of her life. Here is the conversation between the two participants:

....You know, to have somebody working with you one to one...the impact that that can have on you...really is...immense... And I do think that it's had a lasting effect on the way that I approach things...and...feel about myself. Hmm...Top that. (Participant 2, TCM HC group)

...definitely better, definitely feel...happier and easier to deal with stuff...really been a great help. And that I would say is absolutely down to the consultations...just feeling emotionally stronger, happier...Yeah. (Participant 1, TCM HC group)

A participant reported that the BMEA treatment did not alleviate her pain, although it made her feel better, more cheerful and relaxed. Here is what she had to say:

...on the day of the treatment, I always felt better ...and then relaxed going home, and yeah, it helped me sleep...well...it's more my wellbeing... (Participant 1, BMEA treatment)

Theme 5: Enhanced coping Skills

Participants in the BMEA treatment group acknowledged that because they experienced less pain, they were more positive and were able to function and cope better. This participant captured the essence of the group's discussions:

Yeah, I...was a lot more positive and a lot more pain free, and it was just... a lot easier to get through the week knowing that even if it was just a few hours of less pain...it was just so much easier to cope with everything...(Participant 5, BMEA treatment group)

Another participant reported that she felt more able to cope because the intervention had shifted her focus from dealing with her pain to her emotional wellbeing, thus she felt more positive and happier:

Yeah,... I felt much more able to cope...just looking at my emotional wellbeing and...stuff that I never considered. I'm so focused on trying to deal with the pain all the time... Being able to sleep and things like that...were massively helpful to me...I had it, 'cos it had been a month of really, really positive...great...I was a lot more happier. (Participant 4, BMEA treatment group)

Similarly, another participant reported that the intervention coupled with advice on emotional wellbeing, helped her cope better:

...she actually suggested a lot of emotional stuff for me,...Yeah, I...was a lot more positive and a lot more pain free, and it was just... a lot

easier to get through the week...it was just so much easier to cope with everything...(Participant 5, BMEA treatment)

Benefits of NHS standard care as perceived by the NHS SC group

Theme 1: Adverse effects of medications

Participants in the NHS SC group expressed frustrations and dissatisfaction with the ineffectiveness and multiple unacceptable side effects of their medications:

...I've been put on various courses o', like, Zoladex and so forth...Came off it and I had the usual sort of, painkillers.... I was put on a second round of Zoladex. After that round I started to get even more...and my hips, I couldn't move...for the pain in my hips. And that was sore...so for me, it was quite frustrating...going down that route and I didn't find...what I was getting was giving me much relief...if anything...I was probably going...the opposite way. (Participant 2, NHS SC group)

Yeah, because every time you take something, you can see all the side effects... (Participant 1, NHS SC group)

Some participants complained of loss of memory, feeling "groggy", dry mouth and constipation:

...if I've had to take top up painkillers, then half the time I don't know what I'm speaking about...and I can't remember anything...I've got a lot of side effects going as well as the... 'Cause the...actual problem itself...so I don't have to...take so many of...you know, sort of, morphine and...Um...and then you have to take drugs for the side effects... So then you end up making...you're...even more groggy the next day. (Participant 1, NHS SC group)

Theme 2: Frustrations at the ineffectiveness of medications

Participants reported that their oral medications had been ineffective in dealing with their CPP:

... It's been years like that and...there's no improvement...this treatment hasn't changed anything...it's just been getting worse and worse... (Participant 3, NHS SC group)

...I couldn't move...for the pain in my hips. And that was sore...so for me, it was quite frustrating...going down that route... (Participant 2, NHS SC group)

...but it's still all about the drugs and managing the drugs...It's...it's...nothing else. And it's very frustrating...for somebody who never took a paracetamol. (Participant 1, NHS SC group)

Theme 3: Heavy reliance on drugs

Participants in the NHS SC group felt that there was too much reliance on drugs to manage their CPP:

...um, I think...they're too heavy reliant on drugs and change...of drugs and give you more drugs and try that.....injection. They should be working hand-in-hand wi' comple...When I say 'complementary'...I mean things like...Yes. Aromatherapy...Yes or...Reflexology...part of a package rather...than just the drugs....alone (Participant 2, NHS SC group)

That's...I just do think there's so much...emphasis...on the drugs... (Participant 1, NHS SC group)

Theme 4: Services that are helpful

Participants reported some services that were helpful:

...I do get very good support from my GP¹...and from my CPN². And...I have to admit they have been very good and they've been very on the ball with... (Participant 1, NHS SC group)

I find the pain group more helpful...than anything else. ...Feels like you're helping yourself...(Participant 3, NHS SC group)

I found the support from the pain team good...They're tried to point me in the direction...er, cutting out different things in my...diet (Participant 2, NHS SC)

Semi-Structured Telephone Interviews

The majority of the participants responded favourably to the methods of recruitment, randomisation, intervention and assessment tools. Two participants in the TCM HC group expressed disappointment at not being randomized to the BMEA treatment. One participant in the BMEA treatment group found the questionnaires challenging due to dyslexia.

¹ GP = General Practitioner

² CPN= Community Psychiatric Nurse

DISCUSSION

This study reports primarily on the qualitative findings of a three-armed feasibility RCT on CPP in women using a mixed methods research. The embedded three focus group discussions captured the participants' perceived benefits of the BMEA treatment, TCM HC and NHS SC. Thematic analysis of the focus group datasets revealed five shared themes in the BMEA treatment and TCM HC groups: reduced pain, enhanced sleep, energy, wellbeing and coping skills; and in the NHS SC group there were four themes of adverse effects of medications, frustrations at the ineffectiveness of medications, heavy reliance on drugs and services that are helpful. Semi-structured telephone interviews showed a favourable trial experience. **On the basis of the recruitment, retention and acceptability of the study to the participants, our feasibility study supports a future phase 3 large clinical trial.**

There are both limitations and strengths in our trial. The demonstrable strength is in the mixed methods approach in that we captured the rich and invaluable experiences of the participants. Furthermore, unlike most acupuncture studies^{14, 37}, our trial did not rely on a set of pre-defined acupuncture points that were used throughout the study. Rather, the meridian BMA used a systematic approach to acupuncture point selection that were tailored to each participant's exact pain location. Despite these strengths, the low attendance in TCM HC and NHS SC focus groups rendered the overall findings less robust than expected. **Interestingly, attendance to the TCM HC intervention was also low compared to the other two groups.** It is possible that those who reported therapeutic benefits were more enthusiastic about sharing their experiences and thus attended the focus group discussions. The absent participants may or may not have benefited from their respective treatments.

Nevertheless, the focus group discussions' findings when evaluated together with the quantitative results, gave us a more holistic overview, underscoring the relevance of a mixed methods research. Indeed, these findings, although not definitive, are important because, to our knowledge, this is the first trial with an embedded qualitative component that provides insights into the perceived benefits of a health consultation through the lens of Chinese medicine (TCM HC alone), and the BMEA + TCM HC (BMEA treatment).

The perceived pain relief experienced by the BMEA treatment group was consistent with other studies' results¹¹⁻¹³, and appeared to lead to enhanced sleep, energy levels, moods and a sense of wellbeing as well as the ability to cope better. These qualitative findings were similar to those of other studies by Paterson²⁷ and Gould³⁸, and complemented some of our quantitative results. For example, a higher proportion of the participants who received the BMEA treatment had a clinically significant reduction in pain and sleep when compared to the TCM HC and

NHS SC groups. The reduction in pain and sleep interference in the BMEA treatment group were also reflected in the per group estimates of effectiveness. Given that most medications used to ameliorate CPP can have unacceptable side effects, it could be argued that the BMEA treatment compared favourably with standard pharmacological interventions.

There might be several explanations for the higher perceived therapeutic benefits reported by the BMEA treatment group: first, this group which received the BMEA needling + TCM HC (BMEA treatment) suggests that both components have therapeutic benefits; second, all three components of an acupuncture treatment (BMEA + TCM HC + context) are therapeutically active; third there might have been a synergistic effect among these three components such as expectation or belief, that positively influenced the clinical outcome such that the sum was greater than the individual components²⁶. This may explain why an individual patient meta-analysis³⁹ on acupuncture for chronic pain conditions showed the greater observed benefit of acupuncture treatment when compared with sham acupuncture and usual care controls, with the effects significantly greater in the former than the latter.

The possible therapeutic effects derived from the contextual factors need to be acknowledged. For example, an enhanced therapeutic patient/healthcare provider relationship or therapeutic engagement (e.g. empathy, compassion trust) have been shown to improve clinical outcomes in acupuncture³⁰ and be much valued by patients⁴⁰. Although studies on the mechanisms of acupuncture on both animals and humans support the notion that acupuncture needling has specific physiological effects⁴¹, a systematic review of placebo (contextual factors) analgesia concluded that placebo analgesia might exist⁴². This begs the question of how best to harness placebo analgesia in clinical practice. One of the most common findings in patients with chronic pain was that they did not feel that they had been heard or had their story listened to⁴³. Adopting a person-centred approach whereby the whole is greater than the sum of the parts, to a clinical encounter may result in better clinical outcomes as suggested in the TCM HC focus group findings and other studies^{27, 44}.

Although a small number of participants attended the NHS SC focus group, the themes that emerged from the analysis highlighted the dissatisfaction with medical treatment: adverse effects of medications, and frustrations at their ineffectiveness in addressing their pain. The adverse effects of medical approaches to CPP are well-documented^{7, 45} and are consistent with our clinical experience. This negative perception of their experience with their medical treatment may be linked to an increase in anxiety and depression by weeks 8 and 12. In contrast the participants who received the BMEA treatment experienced less anxiety and depression.

CONCLUSION

The embedded three focus group discussions gave a more in-depth knowledge of the perceived benefits of the BMEA treatment, TCM HC and NHS SC from the participants' perspectives. The BMEA treatment group reported higher benefits when compared to the TCM HC and NHS SC groups. Of note is the dissatisfaction of standard treatment reported by the NHS SC group. Changes to our feasibility design are needed before conducting a large-scale phase 3 RCT to evaluate the effectiveness of the BMEA treatment for CPP in women.

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Figure 1: Focus Group Discussion Topic Guide

1. Experience of treatment
 - Can I start by asking you about the actual treatment itself?
 - What was involved?
 - Any surprises, or was it pretty much what you expected?
 - What was it like for you coming along twice a week for the four weeks? (acupuncture/health consult/NHS standard care)
 - Any other comments about what it was actually like having the treatment? (acupuncture/health consult)
 - If practical advice was given, did you find it useful in managing your pain?
2. Expectation and belief
 - Did you believe that acupuncture/health consult/standard care would help with your pain?
 - Did you expect that acupuncture/health consult/standard care would help with your pain?
3. Did the intervention (BMEA treatment, TCM HC & NHS SC groups) make any difference in:
 - How you feel in you day to day life? If so, could you expand on your feeling?
 - The quality of life in general? If so, can you explain how it has affected your quality of life?
 - Your pain level? If so, could you expand on that?
 - Sleep quality – get to sleep more easily? Wake early less often? Are you more likely to feel you've had a good night's sleep?
 - Energy levels – able to get more done? For example?
 - Sexual function – more likely to feel like it? Less painful? More enjoyable?
 - Degree of anxiety/depression? If so can you expand on this?
 - Concern about future health – less prone to worrying?
4. Do you have any other comments you'd like to make about the treatment or your involvement in this trial?

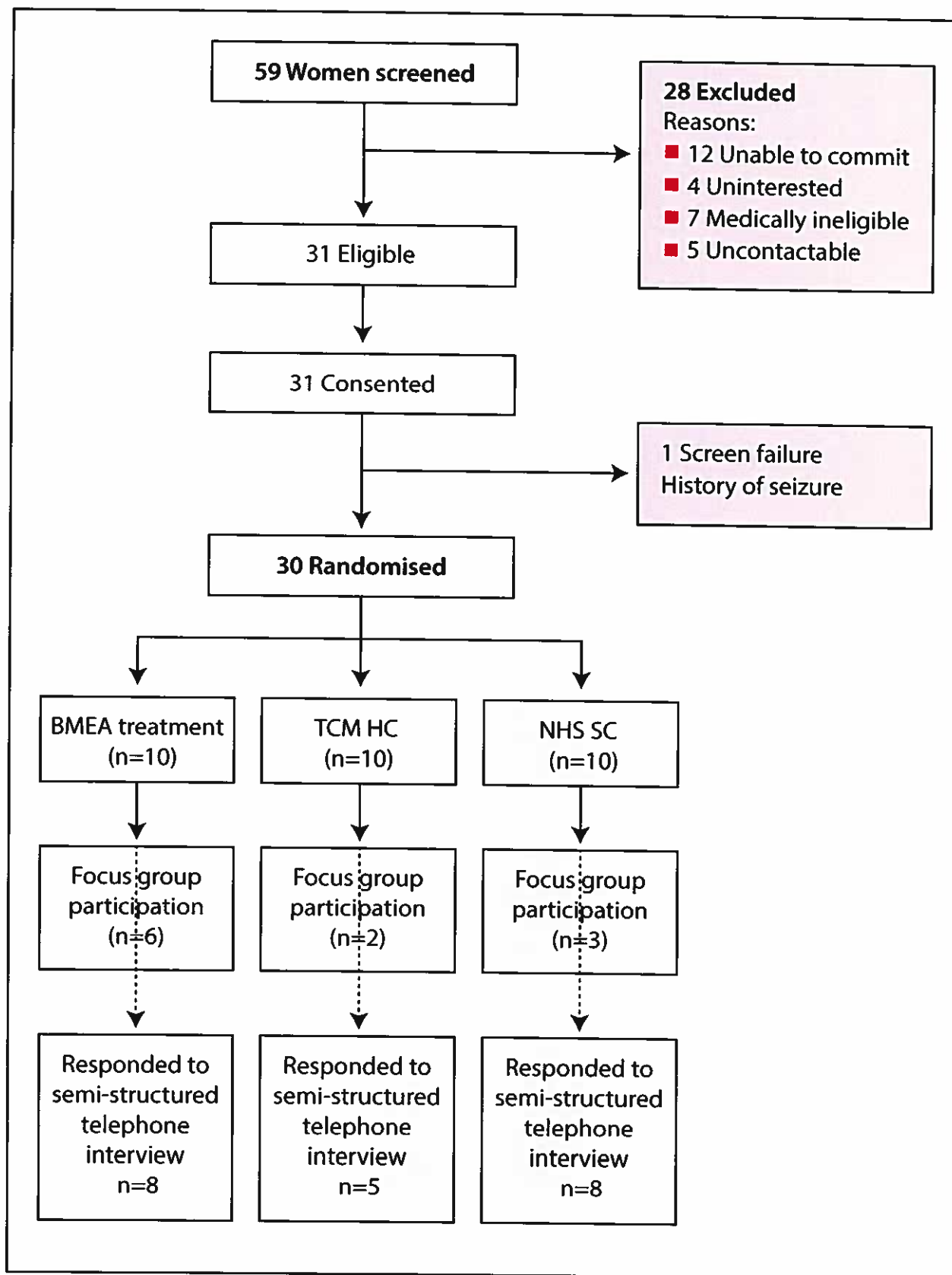


Figure 2. CONSORT Diagram

Table 1. Participants' characteristics

Age	Group 1	Group 2	Group 3
Median	41.5	36.5	42
Mean	40.7 (SD± 9.05)	36.5 (SD± 20.5)	38(SD±8.71)
Range	27-50	22-51	28-44
Marital Status			
Married	3	1	1
Single	1	1	1
Co-habiting	1	0	1
Divorced	1	0	0
Diagnosis			
Endometriosis	6	2	3
Unknown aetiology	0	0	0
Employment			
Medically Retired	1	0	1
Self-employed	2	0	0
Employed	1	2	2
Unemployed	2	0	0
Number of participants	6	2	3

